DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV - 3 2009

Wright Medical Technology, Inc.
% Mr. Gary Henley
Chief Executive Officer
5677 Airline Road
Arlington, Tennessee 38002

Re: P030042
CONSERVE® Plus Total Resurfacing Hip System
Filed: March 12, 2004
Amended: July 26, 2004; April 5, October 9, November 13 and December 3, 2007; January 30, May 8, May 9, May 12, and September 2, 2008; July 29 and August 5, 2009
Procode: NXT

Dear Mr. Henley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the CONSERVE® Plus Total Resurfacing Hip System.

The CONSERVE® Plus Total Resurfacing Hip System is a single use device intended for hybrid fixation utilizing: cemented femoral head component and cementless acetabular component. The CONSERVE® Plus Total Resurfacing Hip System is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients having the following conditions:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/developmental dislocation of the hip (DDH), or
- Inflammatory arthritis such as rheumatoid arthritis.

The CONSERVE® Plus Total Resurfacing Hip System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the

labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at eight years.

Continued approval of this PMA is contingent upon the submission of periodic post-approval reports required under 21 CFR 814.84, at intervals of one year from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you have agreed to provide the following data in post-approval study reports (PAS). Two copies, identified as "PMA Post-Approval Report" and bearing the applicable PMA reference number, should be submitted to the address below.

You have agreed to conduct the following two post-approval studies:

1. Longer-Term Study: This study is designed to evaluate the longer term safety and effectiveness of the CONSERVE Plus Total Resurfacing Hip System. Specific study questions to be answered are: (1) What is the longer-term safety performance of the CONSERVE Plus Total Resurfacing Hip System? (2) What is the longer-term effectiveness performance of the CONSERVE Plus Total Resurfacing Hip System? A single-arm, multi-center, prospective cohort study design with hypothesis testing will be used to determine the 10-year (120-month) survivorship and pain and function levels, as determined using the Harris Hip Score, using the CONSERVE Plus Total Resurfacing Hip System. Patients to be recruited in the longer-term study will include those who were previously enrolled in the CONSERVE Plus Total Resurfacing Hip System investigational device exemption (IDE) study, G990328; are part of the All Enrolled Unilateral Cohort (original shell) as described in PMA P030042, with the exception of the four investigational sites identified in your draft protocol; meet the inclusion/exclusion criteria outlined in the draft protocol; and, have not previously

undergone device removal/revision. The study population will consist of this same cohort of patients, but also include those who have undergone device revision/removal, with at least 229 CONSERVE Plus Total Resurfacing Hip System patients followed through the 10-year post-operative visit. To minimize patient selection bias, you have agreed to take reasonable measures to recruit all eligible patients and will document the reasons for why patients are not enrolled. You have also agreed to take reasonable measures to avoid loss to follow-up and will document the reasons why patients are lost to follow-up. If the follow-up rate is unacceptably low during the 10-year follow-up, FDA will consider other regulatory options to limit loss-to-follow-up, including requiring you to recruit more subjects. Clinical success at 120 months post-operative for each patient will be survivorship, defined as freedom from revision or removal; and, at least "good" function/pain relief defined as a Harris Hip Score ≥ 80. Secondary endpoints, also assessed at 120 months post-operatively, include: radiographic outcome, metal ion concentration, renal function (BUN, creatinine, and GFR), patient satisfaction as assessed by the SF-12 and safety endpoints (device-related adverse events at 120 months post-operative). Safety data will also be collected throughout the study, including but not limited to: all adverse events, including details of the nature, onset, duration, severity, relationship to the device, and relationship to the operative procedure and outcome, reported for these patients. Patients will undergo clinical and radiographic evaluation postoperatively at years 5, 8 and 10. Patients will receive a mailed questionnaire to evaluate pain, function, and patient satisfaction at years 6, 7, and 9. Patients will also have serum levels of cobalt and chromium ions and renal function data collected at 5, 8, and 10 years post-operatively.

You have agreed to submit post-approval study reports, separately for this study, every six months for the first two years and then annually until the study is completed. You must also update your patient and physician labeling (via PMA supplement) to reflect the 5- and 10-year findings of the longer-term study as soon as these data are available, as well as any other time point deemed necessary by FDA if significant new information from the study becomes available.

2. New Enrollment Study: This study is designed to examine the performance of the CONSERVE Plus Total Resurfacing Hip System in newly enrolled patients under real world conditions of use. The specific question to be answered is: What is the performance of the CONSERVE Plus Total Hip Resurfacing system under actual conditions of use? A multi-center, prospective, historically controlled cohort study design with hypothesis testing will be used to determine the 2-year (24-month) survivorship and pain and function levels, as determined using the Harris Hip Score, using the CONSERVE Plus Total Hip Resurfacing System. You have agreed to recruit 4 new clinical sites with a geographically diverse mix of academic, referral, and/or community based sites; and, investigators with different levels of experience using hip resurfacing devices. You have agreed to enroll 183 new study subjects and follow them for 2 years, with a minimum of 155 study subjects followed through the 2- year follow-up visit. You

have agreed to take reasonable measures to limit cumulative loss-to-follow-up and will document the reasons why patients are lost to follow-up. If the follow-up rate is unacceptably low during the 24 month follow-up, FDA will consider other regulatory options to limit loss-to-follow-up, including requiring you to recruit more subjects. Clinical success at 24 months post-operative for each patient will be survivorship, defined as freedom from revision or removal; and, at least "good" function/pain relief defined as a Harris Hip Score $\geq$ 80. The secondary endpoints, also assessed at 24 months, include: SF-12 (MCS & PCS scores), radiographic components (Cup Position, Cup inclination, Cup Migration, Femoral Position, Femoral Angulation, Femoral subsidence, and Acetabular and Femoral Radiolucencies), Metal Ions (Serum Cobalt and Serum Chromium), Renal Function (GFR, Creatinine, and BUN); and safety endpoints (device-related adverse events at 24 months). Safety data will also be collected throughout the study, including but not limited to: all adverse events, including details of the nature, onset, duration, severity, relationship to the device, and relationship to the operative procedure and outcome, reported for these patients. Patients will undergo clinical and radiographic evaluation pre-operatively and postoperatively at 0-60 days, 12 and 24 months. Patients will also have serum levels of cobalt and chromium ions and renal function data collected pre-operatively and at 12 and 24 months post-operatively.

You have agreed to submit post-approval study reports, separately for this study, every six months for the first two years and then annually until the study is completed. You must also update your patient and physician labeling (via PMA supplement) to reflect the 2-year findings of the post-approval study in newly enrolled subjects as soon as these data are available, as well as any other time point deemed necessary by FDA if significant new information from the study becomes available.

You have also agreed to the following conditions of approval:

3. You have agreed to implement a training program, as outlined in the PMA. The training program includes quarterly investigator teleconferences or meetings for the first two years of the New Enrollment study to provide a clinical update to investigators; to discuss study issues including adverse events; and to identify recommendations for improvement of the training program or labeling. If some investigators cannot attend the conference, you have agreed that these investigators will be contacted by telephone or will be sent a feedback form so that individual feedback can be obtained. You have agreed to submit a summary of the minutes of the quarterly teleconferences/ physical meeting/ investigator feedback information as part of the PAS Interim Reports.

You have agreed that the results of the post-approval studies and training program assessment outlined in items 1-3 above must be reflected in the labeling (via a supplement) when the post-approval study is completed, and/or at earlier timepoints, as needed.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval studies. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

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If you have any questions concerning this approval order, please contact Mr. John S. Goode at (301) 796-6407.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health